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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/828,827
Filing Date: April 21, 2004
Appellant(s): MOTYKA ET AL.

Gary P. Oakson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/06/07 appealing from the Office action mailed July 11, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5504055	Hsu	4-1996
6426424	Ashmead	7-2002

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6725427

Ashmead

4-2004

Izumi et al. (Angew. Chem. Int. Ed. Engl. 1978, 17, pp. 176-183).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-40, 44-46, 48, 49 and 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsu (US 5,504,055).

Hsu discloses metal amino acid chelates that can deliver high levels of desirable metal ions to plants and human beings (Abstract; Column 1, lines 44-50). Hsu distinctly claims iron, copper, zinc, magnesium, manganese and calcium as metal ions and glycine as the amino acid thus anticipating instant claims 1-8 (Column 11, lines 45-52; Column 12; lines 12-14 and 18-24 and claims 7 and 8). The mole ratio of metal ion to acid is about 1:2 (Column 2, lines 35-36). Hsu disclose a composition, and means to make the compositions, comprising ferrous iron carbonate/citric acid/glycine to produce an amino acid chelate thus anticipating the addition of citric acid (instant claims 19-21,

29-31, 53 and 54) (Column 3, lines 63-67 and column 4, lines 1-14). Hsu provides methods to synthesize the metal amino acid chelate (instant claims 38-40) (Column 3, lines 63-67 and Column 4, lines 1-14, for example). The Examiner interprets the selection of specific reagents by Hsu to produce the metal amino acid chelate as reading upon instant claims 39 and 40. Hsu administered the iron/citrate/glycine chelate to tomato plants (instant claim 46) (Column 7, lines 56-67 and column 8, lines 1-13). The Examiner interprets the selection of specific reagents by Hsu to produce the metal amino acid chelate for administration to tomato plants as reading upon instant claims 48 and 49. It is the Examiner's position that the method of Hsu et al. is the same as that claimed in instant claim 52, i.e., it results in the same composition.

Claim Rejections - 35 USC § 102

Claims 38-40, 44-46, 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashmead et al. (US 6,426,424).

Ashmead et al. disclose compositions and methods of preparing amino acid chelates (Abstract). The amino acid ligand to metal molar ratio is from about 1:1 to 4:1 (Instant claim 1) (Column 5, lines 31-35 and column 10, lines 24-25). Ashmead et al. disclose iron, copper zinc manganese, cobalt, magnesium, chromium, and molybdenum as metal ions and provide examples of a ferrous glycine chelate, zinc glycine chelate, manganese glycine chelate, magnesium glycine chelate, copper glycine chelate as well as mixed metal/amino acid chelates in the ratios of amino acid ligand to metal ion of 2:1

to 3:1 (instant claims 2-9 and 11)(Column 8, lines 8-25 and 48-67; column 9, lines 5-67 and column 10, lines 1-16). Ashmead et al. produced a metal amino acid chelate and added to the composition maltodextrin, corn-starch and cellulose (instant claims 19, 22-24, 28-31 and 38-40, 44 and 45) (Column 9, lines 29-32). Ashmead et al. disclose that the amino acid chelates can be administered to plants by dissolution on leaves or as a soil treatment thus anticipating instant claim 46 (Column 7, lines 53-63). Obtaining metal ions and amino acids to make the composition reads upon instant claims 48 and 49.

Claim Rejections - 35 USC § 102

Claims 38-40, 43-49 and 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashmead et al. (US 4,725,427).

Ashmead et al. disclose a vitamin and mineral composition comprising amino acid metal chelate with an amino acid ligand to metal ratio of at least 2:1 and a method of preparing the vitamin and mineral composition (Column 5, line 61; column 11, lines 1-23 and lines 53-59; column 12, lines 1-36). The amino acid chelated minerals are selected from the group consisting of calcium, magnesium, iron, zinc, copper and manganese (Column 12, lines 18-22). Glycine is disclosed as an amino acid ligand (Column 5, lines 64-67). Thus, instant claims 1-4 are anticipated.

A powdered mixture of water soluble vitamins was prepared by blending calcium ascorbate folic acid thiamine mononitrate, sodium salt of riboflavin-5-phosphate, niacinamide pyridoxine HCl, biotin and calcium pantothenate (Column 9, lines 15-21).

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The powdered mixture was then blended with powdered lactose. Ascorbate is a salt of ascorbic acid. The Examiner interprets powdered lactose to be a maltodextrin and that maltodextrins can be both fillers and flow control agents thus reading on instant claims 19-24, 44 and 45. In a separate container, ethanol, propylene glycol, vegetable oil, vitamin A palmitate, vitamin D, vitamin E and cyanocobalamin were mixed until dissolution (instant claims 27) (Column 9, lines 24-34). The water-soluble vitamins were then added to the oil soluble vitamins and blended (Column 9, lines 35-43). To this mixture was added amino acid metal chelates and potassium amino acid complex thus reading on instant claims 26, 27, 29-31 and 38-40 (Column 9, lines 44-51). After blending, citric acid (instant claims 18 and 19), potassium bicarbonate and sodium bicarbonate, lime and lemon flavoring and aspartame sweetener (instant claim 28) were added and completely mixed and ultimately granulated (Column 9, lines 52-67). The granules dissolved in water to provide a pleasant tasting flavored drink thus reading on instant claims 15-18, 46, 48, 49, 53 and 54 (Column 2, lines 35-40 and column 10, lines 1-5). It is the Examiner's position that someone had to taste the composition and report on the flavor; any subject can be susceptible to allergens upon exposure to allergens; amino acids can be purchased in pharmaceutically pure form implicitly having no allergens thus reading on the method of instant claims 43 and 52. Subjects can inherently have allergies to at least one of soy, peanuts, tree nuts, crustaceans, finfish, dairy, wheat, eggs, corn, gelatin, whey, chocolate, and strawberries. Ashmead et al. claim the method of preparing the composition (Column 11, lines 53-59 and column 12, lines 1-36 and claim 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 42, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashmead et al. (US 4,725,427) in view of Izumi et al. (Angew. Chem. Int. Ed. Engl. 1978, 17, 176-183).

The reference of Ashmead et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Ashmead et al. do not expressly disclose a composition and method wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared by: 1) a method other than protein hydrolysis; 2) protein hydrolysis and wherein the protein used in the hydrolysis is hypoallergenic.

Izumi et al. teach multiple methods of producing amino acids including enzymatic, fermentation, extraction (protein hydrolysis) and synthetic methods (Page 176, Table 1; page 177, 2.1 Extraction Method; 2.2 Fermentation Method; page 178, 2.3 Enzymatic method; and page 179, Synthetic Method).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to obtain amino acids via one of the methods suggested by Izumi et al. for the composition of Ashmead et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Izumi et al. state these methods are the recent advances in industrial production of amino acids (Page 176, middle of right column)

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' hypoallergenic metal amino acid chelate composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

(10) Response to Argument

Response to arguments over 35 U.S.C. 102 rejections:

Appellant's arguments over Hsu, Ashmead '424 and Ashmead '427 can be summarized by stating that the Examiner has incorrectly understood the instant invention and has a fundamental lack of understanding of making appropriate rejections under 35 U.S.C.102. The basis for Appellant's arguments hinges on the word "hypoallergenic". Appellant asserts that since none of the cited references of record

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positively recite "hypoallergenic" then each and every limitation of the claim has not been met and the Examiner has not properly applied the statutes. Respectfully, the Examiner cannot agree. The Examiner has asserted that the compositions disclosed in the art are hypoallergenic based upon Appellant's own definition of hypoallergenic and that Appellant has not proven otherwise. From page 8, lines 12-18 of the instant specification:

"The term 'hypoallergenic' refers to compositions where care has been taken in formulation and/or production to ensure minimal instance of allergic reactions in a target subject or class of subjects. Hypoallergenic can also refer to a composition that when contacted, e.g., topical, or ingested, e.g., food fortification or nutritional supplement, at customary levels to provide a nutritional, cosmetic, or medicinal effect, the contact or ingestion does not produce an adverse discernable allergic reaction to a target subject or class of subjects." Appellant teaches the types of materials that cause allergic reactions on page 8 line 24 through page 9, line 1: *"The term 'allergen' refers to a substance that causes manifestations of allergy, such as a protein or antigen. The FDA lists eight major allergen sources in the FDA Compliance Policy Guide, CPG 555.250, which includes: soy, peanuts, tree nuts (almonds, walnuts, etc.), crustaceans, fin fish, dairy, wheat, and eggs. Other known allergens that affect a relatively large percentage of the population may include corn, from which maltodextrin is derived, gelatin, whey, chocolate, strawberries, etc."* Therefore, the reasonable conclusion that is drawn from Appellant's own teachings is that compositions are hypoallergenic when "care has been taken in formulation and/or production" to exclude such allergen sources as described

above. None of the cited references teach adding soy, peanuts, tree nuts (almonds, walnuts, etc.), crustaceans, fin fish, dairy, wheat, and eggs and other known allergens including corn, from which maltodextrin is derived, gelatin, whey, chocolate, strawberries, etc. and, therefore, the Examiner can only reasonably conclude that the prior art compositions and methods of making and using the compositions are hypoallergenic and read on the instant claims. Appellant has not demonstrated otherwise and merely argues. The Examiner does not find these arguments persuasive.

Appellant asserts that the cited references do not disclose or suggest the affirmative steps of determining the metal to be hypoallergenic and the amino acids to be hypoallergenic. This falls in the realm of common sense. One of ordinary skill in the art of nutritional supplements is not going to make a metal amino acid chelate for human consumption that contains peanuts, animal dander or other impurities unless it expressly states as much on the label. It is simply common sense that manufacturers of nutritional supplements adhere to *good manufacturing practice* or risk severe penalties and therefore select metals and amino acids that are free from contaminants and use *good manufacturing practice* in the production of such materials.

With regards to the steps of identifying a subject susceptible to a type of allergic reaction and formulating a metal amino acid chelate by selecting amino acid sources and metal sources determined to be hypoallergenic with respect to the type of allergic reaction it remains the Examiner's position that *any subject* is susceptible to a type of allergic reaction. Formulating a metal amino acid chelate by selecting amino acid sources and metal sources determined to be hypoallergenic with respect to the type of

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allergic reaction is simply another way of stating the material is without impurities as would be pure materials. While the exact phrases "identifying a subject susceptible to a type of allergic reaction" and "formulating a metal amino acid chelate" by selecting "amino acid source[s]" and "metal source[s] determined to be hypoallergenic with respect to the type of allergic reaction..." are not explicitly recited in the art they are nevertheless simply inherent/intrinsic in the art. This is common sense. A nutritional supplement manufacturer is not going to contaminate their nutritional supplements with animal dander, bee venom and peanuts. Furthermore, it is common sense not to give a child with a peanut allergy a peanut butter sandwich and by analogy one of ordinary skill in the art would not give such a child a metal amino acid chelate with peanut products in it.

To summarize, from a manufacturing standpoint it is contrary to good manufacturing practice to make products with impurities that could be potentially lethal to the consumers ingesting them without a distinct warning label as having those impurities present and it is contrary to conventional wisdom to administer products with those impurities to individuals with known intolerance issues. Therefore, one of ordinary skill in the art would "determine" the types of impurities in an ingredient, such as a metal or amino acid, before formulating a composition, such as a metal amino-acid chelate, and make an impurity free product and one of ordinary skill in the art would "determine" a susceptible subject, for example a child with a peanut allergy, and not administer a product to that subject with the allergen in it. This is merely common sense.

With respect to the 35 U.S.C. 103(a) rejection over Ashmead '427 in view of Izumi, Appellant renews the argument that none of the cited references positively recite "hypoallergenic" and neither Ashmead '427 nor Izumi teach selecting an amino acid determined to be hypoallergenic or selecting a metal source determined to be hypoallergenic and, for claim 46, neither Ashmead '427 nor Izumi teach identifying a subject susceptible to a type of allergic reaction; formulating a metal amino acid chelate by selecting an amino acid determined to be hypoallergenic and selecting a metal source determined to be hypoallergenic; or administering the hypoallergenic metal amino acid chelate composition to a subject. Respectfully, the Examiner cannot agree for the same common sense reasons described in detail above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616

Conferees:

/Ernst V. Arnold/

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